1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

PANAMOR GEL 1,292 g/100 g (60 g or 100 g pack size)

Diclofenac hydroxyethyl pyrrolidine

Read all of this leaflet carefully because it contains important information for you

PANAMOR GEL is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use PANAMOR GEL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PANAMOR GEL with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What PANAMOR GEL is and what it is used for
2. What you need to know before you use PANAMOR GEL
3. How to use PANAMOR GEL
4. Possible side effects
5. How to store PANAMOR GEL
6. Contents of the pack and other information

1. What PANAMOR GEL is and what it is used for

PANAMOR GEL belongs to a group of medicines called non-steroidal anti-inflammatory drugs.

PANAMOR GEL has anti-inflammatory and analgesic properties. PANAMOR GEL is used to relieve pain and reduce swelling in painful conditions affecting joints and muscles, for example sprains, strains and bruises.

2. What you need to know before you use PANAMOR GEL

Do not use PANAMOR GEL:

- if you are hypersensitive (allergic) to diclofenac and other non-steroidal anti-inflammatory medicines or any of the other ingredients of PANAMOR GEL (listed in section 6).
- if you are using other NSAIDSs e.g. aspirin or other medicines containing diclofenac.
- if you have a condition called porphyria.
- if you have heart failure, established heart disease and/or cerebrovascular disease, e.g. if you have had a heart attack or stroke.
- if you have now, or have ever had, a stomach (gastric) or duodenal (peptic) ulcer, or bleeding in the digestive tract (this can include vomiting blood, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces).
- if you have asthma and experience attacks of asthma after taking acetylsalicylic acid or other NSAIDs.
- if you are pregnant and or breastfeeding your baby (see Pregnancy, breastfeeding and fertility).

Warnings and precautions

Take special care with PANAMOR GEL:

- if you suffer from heart failure or any heart conditions, high blood pressure, diabetes (high blood sugar levels) or high cholesterol (high amounts of fat in the blood),

- caution is required if you are a smoker.
- if you suffer from asthma or any allergic disease, as NSAIDS like PANAMOR GEL can aggravate the condition.
- if you are elderly, or using a high dose of PANAMOR GEL, as it may cause ulcers and bleeding in the gut which could be fatal.
- if you have gut problems such as ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease (where acid leaks into the oesophagus),
- if you have any serious skin reaction like Stevens Johnsons Syndrome or toxic epidermal necrosis (TEN), as these may be fatal. PANAMOR GEL should be stopped if there is any appearance of any rash, lesions or hypersensitivity.
- monitoring is advised when using PANAMOR GEL over a prolonged period such as blood, liver and kidney monitoring.
- if you are pregnant or breastfeeding your baby.
- if you experience muscle weakness or spasms, palpitations, confusion or feeling tired, urinating less often (these may be symptoms of hypokalaemia or renal tubular acidosis).
- PANAMOR GEL should only be applied to the surface of the skin and not open wounds, or open injuries. It should not come in contact with the eyes.
- PANAMOR GEL should not be taken by mouth.
- the area treated with PANAMOR GEL should not be exposed to sunlight.
- it is important to know that the occurrence of systemic side effects, which can be caused by the use of applying PANAMOR GEL with an airtight dressing.
- Prolonged use over large areas of PANAMOR GEL may have systemic side effects. If this continues then PANAMOR GEL must be stopped.

Children and adolescents

There is no experience with PANAMOR GEL and adolescents aged less than 14 years.

Other medicines and PANAMOR GEL

Always tell your healthcare provider if you are taking any other medicines. (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Anti-platelet and anticoagulants (blood thinning tablets) such as aspirin or warfarin.
- Lithium (used to treat some mental problems).
- Oral steroids (an anti-inflammatory medicine).
- Any other non-steroidal anti-inflammatory medicine (NSAIDs).
- Selective serotonin re-uptake inhibitors (SSRIs) (used to treat depression).
- Diuretics (water tablets) and other blood pressure medicine, as PANAMOR GEL may decrease the effectiveness of blood pressure medicines.
- Digoxin (medication used to treat heart problems).
- Quinolone antibiotics (used to treat infections), when used with PANAMOR GEL may cause fits.
- Mifepristone (a medicine used to terminate pregnancy).

Pregnancy, breastfeeding and fertility

You should not use PANAMOR GEL if you are pregnant or breastfeeding your baby.

Pregnancy

PANAMOR GEL may harm your unborn baby during pregnancy and may cause problems during delivery. At around 20 weeks or later in pregnancy PANAMOR GEL may cause kidney problems in your unborn baby, which may lead to low levels of amniotic fluid that

surrounds the baby. This fluid provides a protective cushion and helps the unborn baby's lungs and muscles develop. Complications can occur with low levels of this fluid.

Driving and using machines

PANAMOR GEL can cause dizziness and headache which may affect your ability to perform skilled tasks, if you are affected, you should not drive or operate machinery.
It is not always possible to predict to what extent PANAMOR GEL may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which PANAMOR GEL affects you (see section 4).

PANAMOR GEL contains propylene glycol

PANAMOR GEL contains propylene glycol which may cause mild localised skin irritation.

3. How to use PANAMOR GEL

Always apply PANAMOR GEL exactly as your healthcare provider has instructed you. Check with your doctor or pharmacist if you are unsure. Do not share medicines prescribed for you with any other person.
Confine the use of PANAMOR GEL to adults and adolescents over 14 years of age only as the safety and efficacy has not yet been established in children.

Use the lowest effective dose for the shortest possible duration of treatment.

Apply PANAMOR GEL depending on the size of the affected area. Apply 2 g to 4 g PANAMOR GEL (1 to 2 fingertips) 3 to 4 times daily. The gel should then be rubbed in gently or massaged into the skin in the case of muscular pain.

After application, the hands should be washed, unless they are the area being treated.

If you have the impression that the effect of PANAMOR GEL is too strong or too weak, tell your doctor or pharmacist.

You should consult your doctor if your condition does not improve or worsens within 7 days of starting treatment. The duration of treatment depends on the indication and the response obtained. It is recommended that treatment be reviewed after 2 weeks.

If you use more PANAMOR GEL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use PANAMOR GEL

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

PANAMOR GEL can have side effects. Not all side effects reported for PANAMOR GEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using PANAMOR GEL, please consult your healthcare provider for advice.

If any of the following happens, stop using PANAMOR GEL and tell your doctor immediately or go to the casualty department at your nearest hospital**:**

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,

- blistering of the skin, mouth, eyes and genitals, as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PANAMOR GEL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fever, chills, swelling, sore throat, fatigue, which may be signs of an infection due to low white blood cell count (leucopenia, agranulocytosis, neutropenia),
- decreased number of new red blood cells which can make the skin pale and cause weakness or breathlessness (aplastic anaemia),
- rapid or irregular heartbeat, reduced ability to exercise, wheezing, a cough that doesn't go away or a cough that brings up white or pink mucus with spots of blood (heart failure),
- any sign of ulcers or bleeding in the stomach or intestine, for example, when emptying your bowels, vomiting of blood or black, tarry feces,
- worsening of colitis and Crohn’s disease,
- fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, light-colored stools, joint pain (hepatitis), yellowing of skin and the whites of your eyes, also called jaundice,
- kidney disease or failure,
- extensive changes in the skin with the appearance of redness, scaling, and large bubbles (bullous dermatitis),

- swelling around eyes, ankles and feet, foamy urine, weight gain (nephrotic syndrome).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- vomiting (being sick), passing of wind (flatulence),
- constipation (irregular and infrequent or difficult evacuation of the bowels),
- dyspepsia (painful, difficult, or disturbed digestion), stomach pain,
- ulcerative stomatitis (characterised by swollen spongy gums, ulcers, and loose teeth),
- itchiness, dry skin, rash, redness of the skin (eczema).

Less frequent side effects:

- headache, dizziness,
- high blood pressure, accumulation of fluid in the leg (peripheral oedema),
- increased sensitivity of the skin to sunlight,
- difficulty in breathing, chest tightness or pain, wheezing (symptoms of asthma).

Frequency unknown:

- the oral ejection of gas or air from the stomach known as belching (eructation), diarrhoea,
- burning sensation at the application site, skin peeling (desquamation),
- elevated liver enzyme levels (seen on blood tests),
- discolouration of skin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PANAMOR GEL.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ +27 (0)11 239-6200

By reporting side effects, you can help provide more information on the safety of PANAMOR GEL.

5. How to store PANAMOR GEL

Store all medicines out of reach of children.

Store at or below 25 ºC, in a dry place.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PANAMOR GEL contains

The active substance is 1,292 g of diclofenac hydroxyethyl pyrrolidine per 100 g.

The other ingredients are isopropyl alcohol, Lanol, perfume (Dalin pH), polyethylene glycol, polyethylene glycol monostearate, purified water, Synthalen KP, Synthalen MP, triethanolamine.

Preservative: Isopropyl Alcohol 8,0 % *m/m*

What PANAMOR GEL looks like and contents of the pack

PANAMOR GEL is a white to ivory-white, milky uniform gel with a characteristic odour of isopropanol and perfume.

60 g or 100 g is packed into a white aluminium collapsible tube, sealed with a white, smooth polypropylene screw cap, and placed in a unit cardboard carton together with a leaflet.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

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Hotline: 0800 122 912/ +27 (0)11 239-6200

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33/3.1/0058

Access to the corresponding Professional Information SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Namibia: NS1 05/3.1/0343

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